Summary Minutes of the
U. S. Environmental Protection Agency
Science Advisory Board (SAB)
Air Toxics Research Strategy/Multi-Year Plan Review (ATRS/MYP)
Panel Meeting
July 23-24, 2003, U.S. EPA Building, Research Triangle Park, NC

Panel Members: (See Roster – Attachment A)
Date and Time: 9:00 a.m. – 5:30 p.m., July 23, 2003 and 9:00 a.m. - 4:00 p.m., July 24, 2003 (See *Federal Register* Notice - Attachment B)
Location: U.S. EPA Building, 109 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Purpose: The purpose of this meeting was to conduct a review of the Agency's Air Toxics Research Strategy/Multi-Year Plan. The Review Panel met to: (1) engage in dialogue with appropriate officials from the Agency who are responsible for its preparation; (2) begin to prepare responses to the charge questions; (3) receive public comments as appropriate; and (4) plan the process needed to complete this review.

Attendees:

Chair:	Dr. Fred Miller
Panel Members:	Dr. John Balbus Dr. Joseph Helble Dr. Rogene Henderson Dr. Keri Hornbuckle Dr. Petros Koutrakis Dr. Leonard Levin Dr. Morton Lippmann Dr. Randall Manning Mr. Mark McMillan Dr. Thomas Overcamp Dr. Lauren Zeise
SAB Staff:	Dr. James N. Rowe, Designated Federal Officer Dr. Vanessa Vu, Director, SAB Staff Office

Others Attending:

Mr. Andrew Ballard, BMA, Inc.
Dr. William Boyes, NHEERL
Mr. Phil Bushnell, NHEERL
Mr. Rob DeWoskin, NCEA
Mr. Bob Fegley, ORD
Mr. Jeff Gift, NCEA
Mr. Stephen Graham, EPA/HEASD

Dr. Brian Gullet, NRMRL
Mr. Ralph Larsen, NERL
Mr. Douglas McKinney, NRMRL
Mr. Stephen Mesma, NHEERL
Mr. Ronald Mosley, APPCP
Mr. Dennis Pagano, OAPQS
Mr. Bill Russo, NHEERL
Dr. Chon Shoaf, NCEA
Dr. Michael Stevens, NCEA
Dr. Kevin Teichman (by telephone), ORD
Mr. Tim Watkins, NHEERL
Mr. George Woodall, NCEA

Meeting Summary

The discussion generally followed the issues and timing as presented in the meeting Agenda (See Attachment C). The meeting lasted until 5:30 p.m. on July 23, 2003 and until 4:00 p.m. on July 24, 2003. There were no written comments submitted to the Panel, and there was no written request to present public comments during the discussion.

Introductory Remarks and Welcome

Dr. James Rowe, Designated Federal Officer (DFO), opened the session at 9:00 a.m. and welcomed panel members. He described the process used by the EPA in developing the Air Toxics Research Strategy (ATRS) (See Attachment D) and Multi-Year Plan (MYP) (See Attachment E). Dr. Rowe reported that a full transcription of the meeting was being recorded that would not be certified by the Science Advisory Board (SAB); however, minutes would be provided and certified by Dr. Fred Miller, as Chair of the ATRS/MYP Panel. He also described the process used by the EPA's SAB staff in forming the panel, which is outlined in the document "Overview of Panel Formation at the EPA Science Advisory Board," found on the SAB website. As part of this process, panel members submitted in writing their background, expertise, and activities relating to the Panel's topic, and also provided confidential financial information for review by the Ethics Officer. The Ethics Officer determined that no conflict of interest or "lack of impartiality" exists for any panel member.

Dr. Rowe thanked panel members for their participation under major time constraints and reviewed the meeting agenda. He reported that no written public comments had been submitted and no members of the public requested the opportunity to address the panel. Members of the panel briefly introduced themselves.

Dr. Vanessa Vu, Director of the SAB Staff Office, welcomed panel members and expressed her sincere thanks for their willingness to serve. She reported that the SAB received a request from the Agency to review the ATRS and MYP said that the panel's input and advice is most welcome. She thanked Dr. Rowe and Dr. Chon Shoaf, National

Risk Management Research Laboratory (NRMRL)/National Center for Environmental Assessment (NCEA), for their support.

Dr. Vu stated for the record that although the ATRS lists her name as one of the reviewers, she only saw an earlier version of the strategy years ago and it has been determined that no conflict of interest exists.

Introduction of the Topic

Dr. Fred Miller launched the review by noting that the ATRS and MYP had been developed over a long period of time, and he said that it was evident that there had been major delays in bringing it forward. He reminded the Panel that there were nine specific Charge Questions (See Attachment F) to be evaluated during the two-day meeting, but he encouraged panel members to look for any omissions in the ATRS and MYP provide advice to the Office of Research and Development (ORD) on these matters.

Presentation of Overview of ATRS/MYP

Dr. Kevin Teichman (ORD) commented by telephone on the ATRS/MYP from the EPA perspective. ORD has prepared 16 MYPs on desired research to address scientific questions for future decision making. ORD has identified specific research goals, timelines, and expected outcomes of completed research projects. Through the MYP, both short-term research outcomes for clients and long-term research goals can be identified. Annual targets that address long-term goals are contained in the MYP, which provide a means to review and evaluate performance. The MYP is designed to compliment the ATRS.

Dr. Teichman described the ATRS as delineating research priorities for ORD, and he said it was written with the assumption of a full budget appropriation. The ATRS identifies all the research questions, and the MYP illustrates what EPA will do with a 100 percent commitment of resources. He stated that the charge to the panel is to provide feedback for inform future drafts of the MYP rather than going back and correcting the current draft. Dr. Teichman expressed his appreciation to panel members for their time and effort.

Dr. Shoaf presented an overview of the ATRS and MYP SAB Review, summarized by slides (See Attachment G). He said development of the ATRS began in 1999 with efforts by the Office of Air and Radiation (OAR), ORD, the National Health and Environmental Effects Research Laboratory (NHEERL), NRMRL, Office of Science Policy (OSP), and others. The ATRS and MYP are designed to identify ORD's air toxic resources and to answer many questions about what is expected under the Clean Air Act Amendments (CAAA), which mandate EPA to regulate and control air toxics. Annual research planning is conducted through Research Coordination Teams (RCTs); Dr. Shoaf reported that the OAR team currently is working on MYPs for FY2005 and beyond.

In reviewing the history of ATRS and MYP development, Dr. Shoaf stated that after the CAAA of 1990, the Agency was required to identify the 30 most hazardous air pollutants (HAPs). The so-called "Dirty 30" list was finalized in 1998 after examining both emissions and toxicity and is actually comprised of 33 HAPs. At the same time, 130 source categories were defined. It was determined after developing the first round of MYPs that formal reviews were needed, and in 2001 long-term goals (LTGs) were added to the MYPs.

Dr. Shoaf clarified that FY2003 Air Toxics budget of $20 million is roughly broken down as follows:

Health Effects (NHEERL)	$ 4.3 M
Exposure (NERL)	$ 4.6 M
Risk Assessment (NCEA)	$ 3.6 M
Risk Management (NRML)	$ 1.7 M
Grants (NCER)	$ 1.9 M
Administrative (Personnel)	$ 3.8 M

A panelist asked about the strategy for dealing with outside sources using grants since EPA clearly cannot achieve all of the research goals on its own. Dr. Shoaf responded that the Agency has representatives to the Health Effects Institute (HEI), which coordinates the Science to Achieve Results (STAR) Grants program, and other groups. He said the original motivation behind the grants program was to add research from the academic world. Grants are now a separate program and he added that there are currently no STAR Grants for air toxics. In response to a panelist's question, Dr. Shoaf said grants would resume next fiscal year, since efforts failed to reinstate them this year. He also directed the panelists to Section 5, Additional Research Needed, of the MYP that outlines research ideas suited for grants.

In response to a question, Dr. Shoaf stated that the research staff is comprised of approximately two-thirds scientists and one-third support staff, which includes secretaries, computer specialists, library personnel, and researchers. A panelist expressed his belief that technical staff should not be listed as "overhead" because it does not give a true picture of the nature of the research work.

Dr. Shoaf provided an overview of each chapter in the ATRS and moved on to a presentation of the MYP.

In discussing the Critical Path for LTG 1, "Reduce Uncertainty in Air Toxics Risk Assessment," Dr. Shoaf clarified that the dates listed for the research indicate culmination of research rather than initiation of research. A panelist asked why the risk research is based mostly on chronic effects instead of acute effects and further asked why the end of the research is not earlier than 2008. Dr. Shoaf replied that most of the chronic effects data are in place, but the research on acute exposures cannot be completed before 2008.

In response to a panelist's questions, Dr. Shoaf explained that community-level research, part of LTG 1, has a 2010 endpoint, and it is anticipated that there will be adequate funding, although Section 5 indicates additional research is desired to enhance the existing plan. The community-level research primarily addresses toxics emitted into the air and inhalation hazards in support of OAR.

Dr. Miller inquired if there were any means to provide assessments on an intermediate scale to determine progress. Dr. Shoaf responded that some slides later in the presentation concerning Annual Performance Goals (APGs) and Annual Performance Measures (APMs) address this type of feedback (Sections 6.1 and 6.2 of the MYP). Dr. Miller asked if a crossover could be established to link funding with these intermediate assessments. Dr. Shoaf replied that APGs and APMS were never intended to be associated with funding.

While reviewing the major research activities of the acute approach, a panelist asked whether ORD had some evidence that was driving the research on acute exposures. Dr. Shoaf said that SAB requested it through the National Scale Assessment because acute exposure becomes more important as residual risk is addressed.

A discussion ensued of accidental/burst exposure studies and batch exposure studies. An EPA staff member indicated that research is moving from cancer-driven programs to non-cancer-driven programs, e.g. shipbuilding, and he said that primarily batch exposures are being researched. A panelist observed that there is a lot of work being done in the occupational area and by the military. Another EPA staff member made the point that events surrounding September 11, 2001 (9/11) have led to a lot of activity on how toxic exposures affect the workplace. Dr. Miller noted the apparent inconsistency between opinions about the level of accidental versus batch exposure studies and he said this could be discussed further during the appropriate stage of the document review.

Dr. Vu stated that both social and acute exposures must be studied, not necessarily accidental exposures but the effects of acute exposures.

A panelist expressed his belief that the decision to apply Maximum Achievable Control Technology (MACT) standards is questionable and a waste of resources that is not supported by experience. He further noted that in terms of 9/11, it is unknown whether any chemicals had a specific effect.

Dr. Shoaf addressed LTG 2, "Implement Risk Reduction of Air Toxics," and stated that Appendix 1 of the MYP lists 55 Priority Air Toxics and the status of dose-response assessment and Integrated Risk Information System (IRIS) development. Dr. Vu stated that some of the dose-response assessments being considered for peer review within the major research activities of residual risk include formaldehyde, acetaldehyde, perchloroethylene, tetrachloroethylene, and methylene, and others. In response to a panelist's question, Dr. Shoaf said that $ 449,000 has been committed for air toxics in assessment centers and the RTP divisions.

Dr. Shoaf concluded his presentation by stating that the MYP LTGs emphasize an acute assessment approach, community assessment tools, and regulatory support. He pointed out that many additional research needs have been identified and listed in the MYP but remain unfunded.

A panelist noted that the documents do not address the expertise and specific disciplinary skill sets needed to conduct the research programs and he asked to what extent the current Agency skill set affects the ATRS. Dr. Shoaf responded that the program is not based specifically on the current skill set but rather each lab is asked to assess their future needs.

Another panelist asked what lessons had been learned from previous MYPs. Dr. Shoaf referred to Section 4, "Progress to Date," as an indication of successes through FY2002-2003 that illustrates ORD has never failed to meet an APG.

General Discussion of Report

Dr. Miller asked each panel member in turn to give their general reactions to the ATRS/MYP before discussing the charge questions.

A panelist recalled that a workshop had been held several years previously on air toxics and risk assessment, but he noted that no reference had been made in the ATRS/MYP to the work of the panel in reviewing original data on risk assessments and dose-response relationships. He expressed his belief that the EPA uses risk data that are often biased in a conservative sense to the point that its credibility is at issue when risks are overstated. He specifically cited data on polyvinyl chlorides (PVCs) and particularly asbestos as instances where the claims of exposure levels and risk are irrationally high and unduly frightening to the public. Unbiased risk characterization must be used, he stated, and cost-benefit analyses cannot be based on conservative estimates. The panelist argued that unless the Agency addresses this issue, the whole exercise of developing the ATRS/MYP is a sham. He commended the authors for their work on the document, however. Dr. Shoaf responded that there were numerous meetings and workshops to review and select from for the report, all of which could not be included. He said there is work being done in the health effects lab to improve methodologies. Mr. Bob Fegeley (OSP) stated that the conservative estimates in dose-response analyses are guidelines that are Agency-wide and must be addressed at that level. He acknowledged that although the Agency is moving to correct these problems, the pace may be slower than what the panel desires.

Another panelist raised the issue of air toxics such as dioxin and others that enter the body by means other than inhalation and that produce chronic effects, and asked what work OAR was doing in this area. Dr. Shoaf responded that other projects outside OAR were addressing this issue and cited research on mercury as an example. Given the list of 188 HAPs, some panelists were concerned about being able to add new chemicals or emphasize certain toxics as circumstances change. Dr. Shoaf said that other chemicals can be added to the list but noted that it is not a very active process given limited resources; ethanol was added by a special request. A panelist noted that current

experience helps the scientific community learn about new chemical hazards and allows some means of interpretation for future risks. Dr. Shoaf emphasized that air toxics research should not be used to make direct links to other chemicals. Mr. Tim Watkins (NHEERL) stated that ORD has ongoing studies that can possibly determine emerging chemicals, and he cited the water program (fish tissue research) and work on polybutylene terephthalate resins (PBTs). A discussion ensued on the importance of being able to track research in other branches of EPA that relate to air toxics to ensure that chemicals such as polychlorinated biphenyls (PCBs) are not being "lost." Panel members recommended that the linkage between the air toxics program and other EPA research programs should be made more explicit.

A panelist agreed that the issue of degree of bias in risk assessment is a good one given the series of evident biases, and she noted that there is a lot of research being conducted outside EPA to address the issue.

Dr. Miller remarked that there are clearly data gaps in the ATRS/MYP and that there are more "science" needs that cannot possibly be fulfilled with the meager $20 million budget.

Another panelist concurred with Dr. Miller, stating that the ATRS covers all the relevant areas very well but that the science to support the program cannot be done with $20 million, and she suggested modeling as a possibility with the appropriate science to support it.

A panelist stated that there is a debate on using risk assessments to predict toxicology and he said that we perhaps are a decade away from doing this comfortably, although there are relevant public health approaches that can be used. The list of 188 toxics has already been reduced to a focus on 33 toxics so the science to do these assessments is available, and he said there is probably a regulatory rather than a public health reason that we are not moving on to risk management.

Another panelist agreed that the ATRS/MYP does a good job of identify and laying out the issues, but added that the intersection with other Agency MYPs should be given so that a realistic view of Agency-wide activity can be easily determined.

A panelist commended the EPA staff for providing a clear, comprehensive overview through the ATRS/MYP of what the Agency would like to accomplish but he agreed with previous comments that $20 million is really inadequate given the listed needs. He asked whether or not metals were covered in other MYPs since they are mentioned only three times in the ATRS/MYP. Dr. Shoaf responded that this is a key area to address and it should not be assumed that metals are being covered elsewhere.

In response to earlier discussion, Dennis Pagano, Office of Regulatory Review (ORR), explained that the list of the 33 toxics does not necessarily constitute those with the highest toxicity or carcinogenic potency, but rather it reflects the amount of information EPA has on given chemicals. Community assessments are ongoing. In response to a

question, Mr. Pagano said that OAR is not conducting epidemiology studies in air toxics. Another EPA staff member stated that the cardio-pulmonary effects of metals are being researched.

General discussion ensued of the HAPs lists. Panelists agreed that it must be a dynamic list that is actively updated by adding and deleting toxics as necessary. Dr. Shoaf stated that the CAAA allow such updates but the bureaucracy often prohibits action. It was noted by EPA staff that a national assessment of HAPs is planned in three-year cycles. A panelist suggested a strategic approach for the Agency, in which toxics would be removed from the lists if the risk is less that 1 in 1 million (*de minimus*). Dr. Miller concurred and asked EPA staff whether this approach is being used or has been used in the past. A staff member replied that it has been done on a source category basis but not a "per chemical" basis. A panelist suggested that Mr. James DeMocker (OAR) may have documents from the workshop mentioned earlier that could provide insight into how such a program might work. Another panelist stated that some compounds, such as PCBs, have unclear sources and she asked whether or not orders of magnitude in terms of air toxics in rural areas are considered part of the strategy. A staff member responded that there is information on emissions and cancer versus non-cancer data, and it will be a future consideration as inventories improve. However, if the source of a toxic is unknown it will not be on OAR's "radar screen." Dr. Shoaf clarified that a toxic must meet a very low threshold to be included on the HAPs list: 1) did it occur in the air; and 2) does toxicity occur. The panelist expressed concern that the existing program does not truly allow for identification of new sources of toxics. Mr. Phil Bushnell (NHEERL) stated that ORD does not view adding to and subtracting from the HAP lists as their job *per se.* For example NHEERL is conducting animal/human studies to assess uncertainties rather than particular chemicals.

Discussion turned to Table 9 in the ATRS, "Crosswalk of Chemical Structure Groups and Priority Program Air Toxics" (Attachment D, page 41). In response to a question, Dr. Shoaf explained that Table 9 provides an example of how things crosswalk among the various EPA offices to ORD and is not an exclusive list limited to the 33 toxics. Some are Indoor Air programs, for example. A panelist commented that the table illustrates that ORD "serves many masters."

Another panelist noted that the phrase "reducing risks" appears repeatedly in the ATRS/MYP yet the CAAA defines residual risks within air toxics as cancer risk and defined a range of acceptable risk to be studied. One key is the risk tools and how they will be developed. According to the ATRS, the EPA plans to do epidemiology studies, but it does not indicate how uncertainties will be dealt with. The panelist expressed his belief that the scientific means to be used in addressing uncertainties should be explicitly stated. Dr. Shoaf responded that a lot of ongoing work within numerous projects addresses uncertainties even though it is not specifically stated in the ATRS.

<u>Discussion of Charge Questions</u>

After breaking for lunch, Dr. Miller introduced additional panel members who previously had been absent due to airport delays. He went on to explain that a draft response to the charge questions would be written during the next afternoon's session, which would be circulated for comments with a specific deadline included for comments.

Discussion of Charge Question 1: Does the research strategy provide a sufficient regulatory and research context? Is it on target in identifying and addressing the expected research needs of the air toxics regulatory program? Is the primary purpose of the ATRS of improving the science underlying the National Air Toxics Assessment (NATA) Program appropriate?

The lead discussant began by commenting that question 1 contains three specific questions (listed above). To the first question, "Does the research strategy provide a sufficient regulatory and research context," his answer was "yes." To the second question, "Is it on target in identifying and addressing the expected research needs of the air toxics regulatory program," his answer was "no, there is inadequate recognition in the document that current methods are not suitable given the overly conservative estimate of risks." Further, the research caps make the ATRS unsuitable for risk communication and risk management except for *de minimus* risk. More focus is needed on methods. To the third question, "Is the primary purpose of the ATRS of improving the science underlying the NATA Program appropriate," his answer was "yes, the purpose is appropriate but the program weakness previously expressed must be addressed first."

Dr. Miller asked panelists to comment on elements pertinent to crafting a specific response to the charge questions for the EPA. A panelist asked whether the panel was charged with assessing the list of 33 toxics, and Dr. Miller responded that he viewed the reference to the list more as background and not as a point of comment. Another panelist asked that previous comments expressing concern about adding and subtracting toxics from the HAPs lists be incorporated into the panel's response. In clarifying the SAB's charge to the panel, Dr. Vu stated that the ATRS lays out the overarching objectives in terms of regulatory need with the Agency providing a context for an overall approach. Dr. Miller suggested that additional comments can be included in the panel's report as addendums, without specifically incorporating them into the document. Because Charge Question 1 is so general, Dr. Miller will consider including comments about the limitations of the list of 33 toxics, and he asked a panelist to provide language to this effect.

A panelist addressed the issue of the bias in EPA's risk assessments from a different standpoint, and she said that in many cases the risks are understated rather than overstated. She offered to provide some written examples to illustrate the point and she suggested that the panel report discuss bias in general. She also noted that the ATRS does address EPA's priorities. Another panelist concurred, but suggested that there could be more clarity.

Dr. Miller assessed the preliminary reaction to Charge Question 1 as generally positive but noting specific deficiencies about bias and the limitations of the HAPs list. A

panelist asked for clarification about the list of HAPs and whether there are provisions for expanding the list. Dr. Shoaf responded that ORD has not taken advantage of the opportunity to expand the list, although it can be done, but rather has only removed substances from the list. Dr. William Boyes (NHEERL) stated that there is a process for adding toxics to the list. Requests to remove toxics usually come from industry, which has a lot of money for research; however, this is not always the case for those wanting a substance added. In response to a panelist's question, Dr. Boyes said that EPA does not have an active program to add toxics to the HAPs list.

A panel member observed that while Strategic Principle 2 of the ATRS is to "focus research and development on the greatest risks to people and the environment," the major risks to the population or the environment are never identified. The Agency has not said what the top five most toxic substances are, for example, but rather has several lists and crosswalks. The priorities should be very clear, he said. Other panelists agreed that the lack of clarity on this point should be corrected.

Discussion of Charge Question 2: Do the summary key questions and research needs comprehensively address the important research that should be undertaken, given the scope of the ATRS?

The lead discussant led off by noting that many key questions are addressed but some critical areas such as maintenance of the HAPs list and air toxics with unclear sources are not addressed. The MYP is more focused than the ATRS overall, she said, and both emphasize only those items related to the regulatory program rather than the broader questions not covered by regulation. She pointed to the inclusion of indoor air as a welcome change. She expressed her belief that the series of questions do not help with establishing priorities, core capacities, or research that can help leverage other research programs.

A panelist commended the inclusion of key question 4 regarding screening questions and asthma. She suggested that there currently is enough knowledge to study exposures to mixtures of compounds rather that single-source exposures. In the past, the focus has been on single compound exposures but it is more forward-thinking to examine mixtures, she said.

Another panelist concurred with the lead discussant's assessments, noting some opportunities may be missed by continually relying on risk as defined by MACT.

A panelist commented that there are very basic research needs in terms of analytical methods relating to exposures, computer models, and ultimately risk assessment within OAR. These are critical core issues that need to be improved in OAR and are not adequately reflected in the ATRS, he said. Dr. Shoaf responded that ORD is very aware of the analytical needs, which are somewhat laid out in MYP Section 5, "Additional Research Desired."

A panel member suggested that some of the work on analytical methods could be done by small business through the Small Business Initiative (SBI) program, which would save some Agency resources.

A panelist suggested that, for clarity, each table should list what specific research questions are being addressed.

Dr. Miller stated that he would have preferred to see the key questions in priority order rather that alphabetical order so that the priorities are not so diffusive. He commented to Dr. Shoaf that the recommendations reflected in the discussion were intended for future versions of these documents and not as instructions to go back and change the current ATRS/MYP. He expressed his hope that the panel was not coming across as overly critical of the EPA staff; the aim of the panel is to address the critical lack of funding and provide advice for the future.

A panel member asked if it is the charge of the panel to assist in developing research priorities. Dr. Miller responded that the charge to the panel is more general but he said specific ideas can be discussed if there is consensus to do so. The lead discussant said that key items within this charge question can be identified and circulated to the panel for comment.

A panelist expressed his discomfort with classifying toxics by chemical compound, believing it to be a bureaucratic rather than scientific classification. He particularly mentioned metals. Dr. Shoaf responded that many chemists worked together in developing classification and he said several other methods were rejected as inadequate. He indicated that this approach provides a method of narrowing the list of 188 HAPs chemically to a more manageable size, but he said that the groups could be changed if the panel believes the correct groups were not chosen.

Dr. Miller turned to a preliminary discussion of the aspect of Charge Question 5 that relates to grouping ("Is the draft ATRS approach of grouping air toxics [Strategic Principle #1], first by chemical characteristics and then by regulatory need, appropriate, and what other approaches might be explored to efficiently group air toxics?") to determine if Charge Question 2 should be modified to include grouping. The lead discussant for Question 5 remarked that given the way the question is posed, it is an appropriate way to group air toxics but the key factor is that there are more appropriate ways to determine how research should progress. Grouping should not be viewed as an end product but as an intermediate product. Using mercury as an example, he noted that the Office of Water (OW), and the Office of Pollution Prevention (OPP), and others are involved in research in addition to OAR. Priorities will have to be multidimensional, involving risk assessment, regulatory needs, and research needs in other areas.

A panelist agreed that the grouping could be an intermediate step; however, chemicals from the same sources must be considered differently because chemicals in the same groups can have different reactions and effects. He expressed his belief that considering chemicals by sources puts too much emphasis on regulatory factors rather that risks.

Another panelist concurred and she suggested grouping by toxicity areas, e.g. carcinogen, reproductive, etc., because the toxic endpoints are the primary concern. A different panel member expressed concern that many different chemicals would be classified as "other/unknown" if grouping was done by toxicity area.

A NHEERL staff member explained that grouping arrangements were the topic of much discussion; NHEERL has approached the issue by mode of action. Some compounds were easy to group in this manner while others were more complicated. Another staff member noted that dose level is also a problem and he said that the goal is always some sort of activity base.

A panel member commented that one's approach is dependent upon one's viewpoint; for fate and transport considerations, chemical compound grouping makes sense while grouping by source is appropriate from a regulatory standpoint. Another panelist concurred and he suggested that the chemicals could be grouped in multiple ways for varying research purposes. A panelist commented that the groupings should not be based on mode of action because it would be very complicated and unworkable.

Dr. Miller determined that it was the consensus of the panel not to modify Charge Question 2 to include groupings.

Discussion of Charge Question 3: Are all relevant discipline areas, e.g., emissions, health effects, exposure assessment, risk characterization, and risk management, addressed at an appropriate and consistent level of detail, thereby presenting a unified perspective?

The lead discussant stated that for a strategy document, he would affirm that all relevant discipline areas are addressed appropriately except for previous objections expressed concerning bias in risk assessments. He said there was not enough emphasis on risk assessment and he asked if risk assessors had been involved in preparing the ATRS/MYP. Dr. Shoaf responded that he personally was involved along with other risk assessors.

A panelist commented that statistics and mathematical models should be used, yet were not mentioned. Another panelist challenged the premise of Charge Question 3 that all relevant discipline areas must be equal.

A discussion of risk communication ensued. A panel member noted that the Presidential/Congressional Commission on Risk Assessment and Risk Management included stakeholders but they are not mentioned in the ATRS/MYP, and she expressed her support for the Commission's recommendation that members of the community be involved so their concerns can be addressed. Industry is always involved, she added. A panel member noted that Colorado has had a lot of success with getting stakeholder involvement and he said it was an important aspect of decision making. Another panelist commented that the ATRS/MYP does not address the sociological aspects of risk assessment and risk management through risk communications and other means. In

response to questions, Dr. Shoaf stated that there has not been a concerted effort by the Agency in the area of risk communication although it has been discussed in NCEA.

A panel member commended the EPA for stressing exposure assessment for the first time.

Charge Question 4: Are the strategic principles listed in Chapter 2 appropriate, and do they facilitate effective decision making for prioritizing future air toxics research?

The lead discussant stated that there are five strategic principles listed in Chapter 2 of the ATRS, which he reviewed individually.

Principle 1. Increase the usefulness of the research program by grouping air toxics initially based on physiochemical properties to assist in future studies of structure-activity relations (SARs). He commented that this is an appropriate way to start, but is not the "be all and end all."

Principle 2. Focus research and development on the greatest risks to people and the environment. The lead discussant commented that this principle is too broadly stated for implementation and should really be the first strategic principle. It does not facilitate effective decision making. He further noted that there is far too heavy an emphasis on carcinogenesis without addressing the magnitude of public health concerns such as reproductive effects, asthma, and cardiopulmonary impacts that far exceed carcinogenesis. He suggested that a tiered approach is needed for classification.

Principle 3. Focus research on reducing major uncertainties in risk assessment and improving cost effectiveness in risk prevention and management. He stated that the ATRS does focus on decreasing major uncertainties but it is unclear how they will be identified. He suggested coming up with a subgrouping.

Principle 4. Undertake and foster multidisciplinary research. The lead discussant said there is no public health issue today that can be solved by a single discipline, so the principle must be included.

Principle 5. Ensuring an appropriate balance between near-term and long-term research. He said that short-term and long-term are not clearly articulated that therefore one could not really decipher whether there is a balance or not. The problem is mainly a lack of information rather than one of concept and design.

A panelist concurred that the second principle should be the first and he further stated that the first is too specific to be a strategic principle especially since grouping is discussed elsewhere. Another panelist recommended more explanation be provided in support of Principle 4, perhaps expanding more in the MYP.

A panel member raised the issue of acute versus chronic effects after adopting the MACT process and he stated that the Agency needs to make the case that there is cause for

concern. Another panelist commented that there are more non-cancer endpoints and irritant and cardio-pulmonary effects. Dr. Boyes (NHEERL) explained that the Agency has a mandate to review both acute and chronic effects when studying residual risk in all categories. Shipbuilding projects under MACT suggest that there are various compounds that should be evaluated using different benchmarks for community and occupational exposures. In response to a question, Dr. Boyes said the residual risk program does not deal with accidental exposures but rather batch processing issues. Assessing acute frequent exposures is difficult because there is so little information. Mr. Watkins (NHEERL) commented that it is not by chance that various exposures are being monitored and personal exposure studies are being conducted. Some source categories are covered by MACT, such as chromium in metal processing plants. This would be addressed in residual risk assessments, he said.

A panelist suggested some discussion should be added to Principle 4 about uncertainty factors, which in some cases are actually variabilities. Sometimes variabilities are being understated so the language should be clarified. She also commented that research dollars should be used to achieve the greatest decrease in risk and as such research being conducted outside the Agency should be considered. Dr. Miller concurred, noting that cost effectiveness and diminishing returns should be considered.

Charge Question 5: Is the draft ATRS approach of grouping air toxics (Strategic Principle #1), first by chemical characteristics and then by regulatory need, appropriate, and what other approaches might be explored to efficiently group air toxics? Does using the polycyclic organic matter (POM) example (Chapter 3) help explain the kind of research an development activities and project areas that should be expected as the ATRS is implemented, or should Chapter 3 be omitted because we now have an Air Toxics Multi-Year Plan?

The lead discussant commented that groupings should be an intermediate step to prioritization for fate and transport but also for controls. They are already grouped around need. It is appropriate to consider other groupings, e.g., mode of action. Groupings currently may only serve as an organizational structure but they may also have control potential. He also said that research prioritization requires additional effort.

A panelist stated that there is a close coupling between metals exposure and particulate matter (PM) and said the panel must ensure this is reflected in the ATRS. Another panelist commented that there are many cases where research outside this program is mentioned and must be reflected in the ATRS, perhaps as a cross reference. Several panel members concurred, and requested that other EPA research programs affecting air toxics be referenced in the ATRS.

Dr. Miller expressed his belief that these comments would best be covered by adding a special section to the panel's report separate from specific comments on the charge questions since they are more related to the overarching goals.

A panelist noted that a missing piece to the ATRS/MYP concerned leveraging. Dr. Shoaf responded that it was a directive that they simply did not get to but he said it will be addressed.

Another panelist commented that states are finding HAPs that are not addressed. Grouping may be generally appropriate, but states may need assistance in moving forward with them.

In discussing the second part of the charge question on the POM example, Dr. Shoaf clarified that there is no special priority attached to POM but rather it is only to provide an example. He asked the panel members whether they found the example to be helpful. The panel agreed to endorse including an example but with modifications such as cross linking to the MYP and specifying what research projects will be conducted to meet the needs.

The discussion turned to consideration of research projects in the MYP especially in terms of the APGS and APMs. Some panelists expressed concerns that the APGs and APMs were so general as to not be specific to air toxics. Mr. Bill Russo (NHEERL) stated that there is a draft plan with specific projects identified that will achieve the APMs. Dr. Vu clarified that Mr. Russo was referring to an implementation strategy that is not part of the panel's purview. Dr. Shoaf said that the APMs used to be so general that the Agency was criticized but they are more specific now although specific chemicals are not named. He further noted that APGs and APMs are not created until a MYP is developed although general research lines are created.

Dr. Miller suggested that the example in Chapter 3 should include related APGs, APMs, and lines of research. He emphasized that the APGs and APMs are entirely too general and give no indication of how the ATRS is specific to air toxics; in fact, the word "ozone" could be substituted for "air toxics" and the document would still make sense, he said. Another panelist concurred that there is nothing about the issues presented that are specific to air toxics. Dr. Shoaf responded that as they were moving through the MYP, APGs and APMs were being developed and research specific to air toxics was being planned. However, it became apparent that the research was being skewed to regulatory rather than scientific needs so more specific APGs and APMs were included. Dr. Miller reiterated the committee's request that lines of research supporting air toxics be more explicit in the ATRS/MYP. Many panelists agreed that clarity and methods of prioritization were essential to Chapter 3.

The lead discussant summarized that the POM example is worth keeping in part because it is related to wider goals rather than specific to the MYP. However, some extension into the MYP is necessary. The consensus of the panel is to explicitly list the set of needs, apply strategic principles and the state of the science, and enumerate desired outcomes through lines of research to provide a link to the MYP.

Charge Question 6: Are the implementation approaches of developing an air toxics multi-year plan, creation of a cross-laboratory and center air toxics steering committee, and

conduct of scientist-to-scientist meetings on air toxics research sufficient to implement the ATRS?

The lead discussant commented on each of the three aspects of the charge question. First, there is a disconnect between the ATRS and the MYP, and it appears that the priorities expressed in the MYP did not fully come from the ATRS. She also found the MYP to be somewhat insular in that its does not describe how the strategy will be accomplished. She recommended that the MYP include external sources that will help EPA achieve its goals. Second, she commended EPA on integrating the research of the various labs. Third, she expressed support for the concept of scientist-to-scientist meetings and she described it as essential for EPA to meet with external scientists considering the limitations of a $20 million budget.

She commented that the timing of research on mixtures of compounds should not be delayed but rather conducted earlier. Another panelist expressed surprise that the EPA's work on source mixtures through the NERC project was not mentioned. Dr. Shoaf responded that there are APMs on mixtures listed on page 29 of the MYP with an expected completion date of FY 2006, meaning the research would probably begin in FY 2004 with planning underway. Mr. Russo indicated that they are aware of work being done on source-related mixtures, which is briefly referenced in the MYP.

Dr. Miller asked EPA staff to comment on who has the authority to shift dollars and resources as needed to emphasize critical projects, since the information was not contained in the ATRS/MYP. Mr. Bob Fegley (ORD) responded that there is a RCT comprised of representatives from all ORD labs, program offices, and regions. The program currently is in flux, but in the past the RCT populated writing teams on MYPs to provide input on future research programs. He reported that ORD must always be prepared to accept budgetary reductions of up to 20 percent and must identify possible areas to be cut although the actual decisions on reductions are made at higher levels of the ORD and the Agency. In terms of program changes that reflect shifts in scientific or programmatic focus, reviews are conducted every other year. Interim changes are made on an *ad hoc* basis as required. Mr. Fegley noted that there are complaints that this system maintains the *status quo*, so there are discussions underway of possible changes.

A discussion ensued concerning ORD's involvement with HEI. Dr. Miller asked whether a strategy had been formulated for HEI to fill in research gaps where ORD does not have adequate resources. Dr. Shoaf responded that ORD has a representative to HEI so they are informed of research. Through such communication, ORD has pulled back from research that duplicated HEI's research plans and thus saved some resources. Mr. Russo commented that there is an ongoing exchange with HEI and he said ORD engages in the sponsor's meetings.

In response to a panelist's question, Dr. Boyes explained the scientist-to-scientist meetings. They are internal EPA meetings that are advertised throughout the Agency and regions. The meetings present a series of concepts and breakout sessions over 1½ days covering selected program projects. Five such meetings were selected for NHEERL

implementation. The meetings provide a means to develop interdisciplinary research, he said. Mr. Watkins stated that a meeting is being planned for October or November to cover topics of interest in the air program, such as air toxics, personal exposure studies, and possibly the Centers for Disease Control and Prevention (CDC) environmental health tracking system.

Charge Question 7: Do the long-term goals (LTGs) of the MYP align with the ATRS, and do they support the priority needs of the program and regional offices? Would accomplishing these LTGs enable ORD to meet the Air Pollution Research Sub-Objective stated as follows: air toxics research will develop and improve air quality models and source receptor tools, cost effective pollution prevention and other control options, and scientific information and tools to understand and characterize environmental outcomes associated with nationwide, urban, and residual air toxics risks?

The lead discussant opened by referring to the declarative statement preceding the charge question, that the link between the ATRS and LTGs should be seamless. He commented that it is not seamless at all. The MYP poses seven very specific scientific questions then moves to two extremely broad, general LTGs. His answer to whether or not the LTGs align with the ATRS is both yes and no. LTG 1, "Reduce Uncertainty in Air Toxics Risk Assessments," is a broad statement that is followed by a reference to conducting 3-5 community studies, yet there are no specific APGs or APMs addressing this research. He asked for information from EPA staff on these studies.

Mr. Russo replied that the research has been generally identified but all of the cities are not finalized. He anticipates they will be linked to other research programs, especially PM. In response to other questions, he explained that specific funding for 3-5 studies is not final but it is an area still being focused on through implementation plans. There is not enough detail yet to include in the MYP. Air toxics and PM from mobile sources are being considered for epidemiology studies. There is a large exposure study planned for Detroit where an epidemiology study of asthma is being considered, and air toxics will be included to the extent possible.

The panel adjourned for the day at 5:30 p.m.

Thursday, July 24, 2003

Dr. Miller began the discussion on Day 2 at 9:00 a.m., resuming with Charge Question 7.

The lead discussant turned to LTG 2 "Implement Risk Reduction of Air Toxics," stating that its subsequent call for producing 15 tools by 2008 is so vague that it is easily satisfied. There is also little mention in the APGs and APMs about cost-effective pollution prevention. He also commented that it is difficult to separate Charge Question 7 from Charge Question 8.

Dr. Miller asked the EPA staff to provide details of what is meant by "tools." Dr. Shoaf replied that one aspect is core research in developing models and another is dose-response assessments for air toxics. Mr. Douglas McKinney (NRMRL) further commented on risk management tools and improved techniques the community and others can use, modeling, and emissions tools. He added that there are some activities in the area of pollution prevention.

In response to a panel member's question about the needs of the regions, Dr. Shoaf explained that regional representatives provided input in developing the MYP. A major need of the regions is updated Integrated Risk Information System (IRIS) files. The IRIS program brought on several new Full Time Grades (FTGs). Some will be doing air toxics work but are not solely dedicated to that. The same panelist commented that IRIS must be rapidly reviewed for accuracy. Dr. Michael Stevens (NCEA) stated that 300 chemicals have been analyzed within IRIS for updates. Another panelist said that states and regions need numbers, so there is a high demand for IRIS, and she asked whether EPA has considered adapting work done by other groups to help fill in the matrix. Dr. Shoaf replied that the Agency does use outside data and routinely uses risk assessments from other groups, and he cited the Urban Air Toxics report to Congress as an example. A hierarchy has been established, he explained. Dr. Stevens also noted that the OW had used IRIS values developed elsewhere; however, there is a question of how to accomplish peer reviews. Because there may be differences in the way numbers are derived, peer reviews are a key factor in providing consistency.

A panelist asked EPA staff to discuss what regionally-specific issues are being considered. Dr. Stevens reported that a 4-day meeting for the regions on risk assessment will be held in September. Dr. Shoaf said that efforts are ongoing in the area of monitoring to determine what is needed for air toxics and exposure analyses. The ATRS/MYP does not focus on monitoring because that generally is left to the program offices. Mr. McKinney said that ORD helps with network design, and where to place them, especially with PM, but the Office of Air Quality Planning and Standards (OAPQS) and the states ultimately decide where they will monitor.

A general discussion of monitoring programs ensued. A panel member expressed concern that, without more integration through a national effort to match monitoring and modeling, the goals cannot be achieved in a scientifically sound way. He cited acid rain as an example of highly integrated research that the Agency spent years developing. Dr. Stevens responded that such integration is a goal but many other factors are in play. Other panelists strongly urged closer coordination in monitoring programs. One panelist said that state resources are too limited to do methods development, so integrated programs would be very useful from a state perspective. Another panelist stated that compliance monitoring is very expensive for PM and suggested the Agency pursue lower cost alternatives if it is not already doing so. He further commented that the Agency has relied on modeling all its risk assessments but most of the models are not based on validated data. Other panelists commented that this issues returns to the question of how to establish research priorities.

Several questions arose during the discussion that required responses from NHEERL staff not present, so Dr. Miller asked the panel to delay further discussion of Charge Question 7 until later.

Charge Question 8: Are the LTGs appropriate for meeting the Air Pollution Research Sub-Objective (see [Charge Question] 7 above)? Are the APGs and APMs measurable outcomes and outputs, respectively? Do the APGs develop a critical path to achieve the LTG? Do the APMs encompass a body of research that 'adds up" to logically achieve the APG?

The lead discussant commented on each of the four aspects of the charge question. First, victory can be claimed with very little. MYP objective 1.5 would benefit from promised advances in research; however, the question is how much uncertainty reduction is achievable, and is it worth the expenditures? Research objectives must be clear. The 15 tools proposed in LTG 2 have already been discussed by the panel, he said. He stated that cost effectiveness ultimately depends on the credibility of the risk assessments, which is a formidable problem for air toxics. Second, the lead discussant stated that the APGs/APMs table is the most encouraging part of the MYP even though it is short on details. It is a question of priorities with limited resources. He commended ORD for presenting a means to provide accountability. Third, he expressed his belief that the LTGs cannot be achieved with the resources provided. Fourth, the lead discussant commended the ORD for the complex effort required in mapping out the APMs needed to achieve the APGs.

A panelist suggested that dates of initiation of research be provided in addition to completion targets so the various stages of research can be easily evaluated. He also suggested that a bit more background be included in the MYP for clarity.

Another panelist suggested that FTGs be associated with outcomes on a yearly basis and on major projects so critical paths can be followed and activities and outputs can be linked graphically. Other panelists concurred, noting that more information would provide easier evaluation. Dr. Shoaf responded that ORD has an elaborate tracking system to generate quarterly reports. A panelist suggested also including summaries of past MYPs and their impact on current MYPs.

Discussion returned to Charge Question 7 with the arrival of Mr. Watkins (NHEERL). A panel member summarized the panel's concerns over sampling strategies and monitoring methods by asking if any thought was being given to multi-site measurements, long-term averaging, diffusive sampling, or long-term integrated sampling.

Mr. Watkins explained that air toxics monitoring is currently conducted through a recently-initiated state grant program. Pilot studies are ongoing in certain cities. Within research projects, some personal exposure studies are being conducted. Studies using passive samplers are not underway. He reiterated that exposures were being studied in Detroit to determine the relationship between ambient indoor sources and the relative impact of toxic sources on personal levels. EPA is also working to evaluate and validate

the Community Multiscale Air Quality (CMAQ)CT model by applying it to 15 air toxics, and he said this is outlined in the NATA APGs.

Many panel members participated in the discussion. A panelist commended the Agency for including both indoor and outdoor exposures and he also suggested that widespread measurements are unnecessary with appropriate and validated modeling. Another panelist raised the issue of bioaccumulative compounds and she urged that total personal exposures be examined. Mr. Watkins cited National Exposure Research Laboratory (NERL) research in Jacksonville on multi-pathway exposures, but he stated that most studies involved inhalation samples and not blood or tissue. Another panelist reiterated her concern that the lack of multi-pathway research is a serious limitation of the air toxics program because of the limitations posed by the lists of 188, 55, or 33 HAPs. She noted that the importance of the atmospheric pathways is recognized by other sectors of the Agency. Mr. Watkins commented that most multi-pathway modeling work is in the area of pesticides but he is hopeful of expansion to include air toxics.

A discussion ensued of addressing chemicals not on the HAPs lists. Panelists reiterated concerns that compounds were not being listed or de-listed as needed and that there is no way currently to track research affecting air toxics done by other sectors of the Agency. EPA staff members pointed out several research areas fitting this category and clarified various technical points in the APGs/APMs.

Dr. Miller asked for any additional comments from panel members on specific APGs/APMs in order to conclude the discussion of Charge Question 7. A panel member commented that the chronological listing may be internally necessary but he suggested that an APM time line would be more useful to the panel. Another panelist suggested reconsidering the use of the word “determine” in the health endpoints research section since most toxicological research does not make this claim. She further noted that many of the APMs are supporting the program offices but are not really research.

The discussion concluded as Dr. Miller summarized the panel’s call for 1) an additional section specifying research objectives; 2) a structural flow chart; 3) a possible addition of a research initiation date for the APM; and 4) a section summarizing past MYPs and resulting program changes.

Discussion of Charge Question 9: Are these resources sufficient to provide air toxics research that will achieve the LTGs and thereby support the regulatory needs mandated by the CAAA?

The lead discussant opened by noting that the issue of resources had been somewhat addressed throughout the course of the meeting, and he referred to the breakdown contained in Dr. Shoaf’s overview. The lead discussant characterized his reaction that the resources are definitely not sufficient to fully achieve the LTGs. Some inroads can be made but the requirements of the CAAA cannot be met because many areas are lacking from a scientific standpoint.

A panelist suggested that research could be supplemented by other funds that are available through SBIR and the STAR program, and he questioned why more of these funds had not been expended on air toxics. Dr. Shoaf responded that the proposals in the STAR program are more diffuse than ORD would like, and he said they hope to see more focus in future solicitations. Another panelist commented that the STAR program is favorably situated to obtain unbiased development of methods and a focused response. Another panelist commented that internal programs could be leveraged by going to the STAR program and engaging the external scientific community.

Dr. Miller suggested that the ATRS needs a serious infusion of cash and asked EPA staff to speculate on how they would expend double the funding they currently have. Dr. Shoaf answered that for assessments, they would convert to Full Time Equivalents (FTEs) and would double the output of IRIS files for air toxics. Dr. Boyes said that, because current funding for epidemiology studies is inadequate, he would recommend adding air toxics to the Detroit study followed by the Marion, Ohio study of manganese. The community impact of air toxics exposure is not being studied. Mr. Watkins said that the exposure lab would look to improving the atmospheric measuring programs aimed at methods development and source-receptor modeling tools. In the human exposure program, more complete information for modeling tools could be generated and more emphasis could be placed on PBTs. Increased funding would also allow multi-pathway research in addition to the inhalation studies underway. Mr. McKinney suggested a focus on prevention and controls after MACT and more work on the National Toxics Inventory.

A panelist asked whether EPA believed the ATRS/MYP could be accomplished within the $20 million budget. Dr. Shoaf responded that the charge was to propose what could be done within the static budget and he said NCEA could achieve what is contained in the ATRS/MYP but that it would be very close. Dr. Brian Gullet (NRMRL) said NRMRL could not meet the goals with the current funding unless it continued to receive funding from other sources. Mr. Watkins stated that NHEERL can meet most of the goals. In terms of the APMs, it may depend on how "meet" is defined, he added. Dr. Miller agreed that the APMs are broad enough so they may be met but perhaps not with the desired rigor.

Dr. Miller moved to conclude the discussion of the charge questions by reviewing the consensus recommendations of the panel on each question.

Charge Question 1. There was a mixed view from the panel, especially relating to improving the science. Recommendations included explicitly stating long term research goals and addressing bias in risk assessments; leveraging other research; adopting a public health approach; and most importantly, improving risk assessments on dose-response, with specific suggestions on the HAPs list flexibility and priorities.

Charge Question 2. The panel agreed that priorities must be clearly established and programs such as SBIR and STAR must be fully exploited. Other recommendations

were made concerning exposures to mixtures, limitations of the risk assessment paradigm, and analytical measures.

Charge Question 3. There was consensus among the panel to answer in the affirmative while also noting that the list was really one of categories and not disciplines. Recommendations were made to include statistical and mathematical modeling, as well as risk communication.

Charge Question 4. It was agreed that the strategic principles listed were all appropriate but the second should probably come first. The lack of clear priorities made accomplishments unclear. The panel recommended adopting a tiered approach related to *de minimus* risk, distinguishing variability and uncertainty, and leveraging research.

Charge Question 5. The panel's conclusion was that the groupings may be appropriate but different pathways may be needed to consider multidimensional aspects. Recommendations by the panel included combining groupings to act in parallel, adding lines of research to the POM example, and possibly providing an example from each category rather than solely POM. The panel did not recommend the POM example specifically, but did support including an example for clarification. The panel also cautioned that the current groupings may cause some HAPs to be missed.

Charge Question 6. The panel agreed that the missing piece is mixtures, and that sufficiency depends on prioritization. The panel recommended flexibility in switching funds between programs as needed.

Charge Question 7. The sense of the panel was that the LTGs are overly broad, the ATGs are reasonably stated, and the APMs need more focus. The panel recommended: 1) an additional section specifying research objectives and modeling plans; 2) a structural flow chart; 3) a possible addition of a research initiation date for APMs; and 4) a section summarizing past MYPs and resulting program changes.

Charge Question 8. The panel commended the EPA for its work on this question. Recommendations included improving the estimate of risk and dose-response objectives, providing a narrative of how the APGs and APMs fit together graphically, listing and de-listing HAPs, and improving modeling.

Charge Question 9. The consensus of the panel is that the resources provided are insufficient to meet program needs and funding should be doubled. The panel recommended making use of SBIR and STAR programs, undertaking additional epidemiology studies, and listing skill sets that will be needed in the future.

Dr. Miller asked for concluding comments from panel members.

A panelist commended the EPA on the integration that is evident in the program. Other panelists concurred and complimented the staff for moving into new research areas. A panel member commented that ambitious goals were laid out and may in fact have been

set too high given the state of science. Another panelist commented that he did not get the sense that the coordination is easy overall. Dr. Boyes said that his office is continually working on such coordination. He noted that this is the first MYP to go in front of a peer review group and he said others will be reviewed in the future. He also acknowledged that there is a need for better communication since all activities are not recorded in the MYP.

Dr. Miller concluded the morning session by expressing his appreciation to the EPA staff in attendance and stressing the importance of having the staff present during MYP reviews. He stated his intention to advocate convening a similar panel annually or biannually for additional involvement and feedback. He reminded panel members that the afternoon session would be spent drafting a panel report.

Dr. Shoaf thanked the panel for their assistance and guidance.

At 12:15 p.m., the committee adjourned for lunch; the meeting resumed at 1:15 p.m.

Panel members worked on the draft report during the afternoon session.

At about 4:00 p.m., Dr. Miller adjourned the meeting.

Respectfully Submitted:

/Signed/
James N. Rowe, Ph.D.
Designated Federal Officer

Certified as True:

/Signed/
Frederick J. Miller, Ph.D.
Chair

NOTE AND DISCLAIMER: The minutes of this public meeting reflect diverse ideas and suggestions offered by the Panel members during the course of deliberations within the meeting. Such ideas, suggestions, and deliberations do not necessarily reflect definitive consensus advice from the panel members. The reader is cautioned to not rely on the minutes to represent final, approved, consensus advice and recommendations offered to the Agency. Such advice and recommendations may be found in the final advisories, commentaries, letters, or reports prepared and transmitted to the EPA Administrator following the public meetings.

ATTACHMENTS

Attachment A	Panel Roster
Attachment B	Federal Register Notice
Attachment C	Meeting Agenda
Attachment D	Air Toxics Research Strategy Draft
Attachment E	Air Toxics Multi-Year Plan
Attachment F	Charge Questions
Attachment G	Overview of the ATRS and MYP SAB Review

ATTACHMENT A

U.S. Environmental Protection Agency
Science Advisory Board
Executive Committee
Air Toxics Research Strategy/Multi-Year Plan Panel*

CHAIR

Dr. Frederick J. Miller, Vice President for Research, CIIT Centers for Health Research, Research Triangle Park, NC

Also Member: Clean Air Scientific Advisory Committee

OTHER SAB MEMBERS

Dr. Lauren Zeise, Chief, Reproductive and Cancer Hazard Assessment Section, California Environmental Protection Agency, Oakland, CA

Member: Research Strategies Advisory Committee

CONSULTANTS

Dr. John Balbus, Director, Environmental Health Program, Environmental Defense, Washington , DC

Dr. Joseph Helble, Professor and Department Head, Department of Chemical Engineering, University of Connecticut, Storrs, CT

Dr. Rogene Henderson, Director, Lovelace Respiratory Research Institute, Albuquerque, NM

Dr. Keri Hornbuckle, Associate Professor, Civil and Environmental Engineering, College of Engineering, University of Iowa, Iowa City, IA

Dr. Petros Koutrakis, Professor of Environmental Science, Environmental Health , School of Public Health, Harvard University, Boston, MA

Dr. Leonard Levin, Technical Leader, Environmental Sector, Science and Technology Development, Electric Power Research Institute, Palo Alto, CA

Dr. Morton Lippmann, Professor, Nelson Institute of Environmental Medicine, New York University School of Medicine, Tuxedo, NY

Dr. Randall Manning, Environmental Toxicology Coordinator, Department of Natural Resources, Environmental Protection Division, State of Georgia, Athens, GA

Mr. Mark McMillan, Environmental Health Scientist/Air Quality Planner, Air Pollution Control Division, Colorado Department of Public Health and Environment, Denver, CO

Dr. Thomas Overcamp, Professor, Environmental Engineering and Science, School of the Environment, Clemson University, Anderson, SC

SCIENCE ADVISORY BOARD STAFF

Dr. James Rowe, Designated Federal Official

* Members of this SAB Panel consist of

a. SAB Members: Experts appointed by the Administrator to serve on one of the SAB Standing Committees.

b. SAB Consultants: Experts appointed by the SAB Staff Director to a one-year term to serve on ad hoc Panels formed to address a particular issue.

c. Liaisons: Members of other Federal Advisory Committees who are not Members or Consultants of the Board.

d. Federal Experts: "Federal Experts" are federal employees who have technical knowledge and expertise relevant to the subject matter under review or study by a particular panel.

ATTACHMENT B

Science Advisory Board; Air Toxics Research Strategy/Multi-Year Plan Review Panel; Notification of An Upcoming Public Meeting

[Federal Register: July 10, 2003 (Volume 68, Number 132)]
[Notices]
[Page 41132-41133]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr10jy03-68]

ENVIRONMENTAL PROTECTION AGENCY
[FRL-7527-1]

Science Advisory Board; Air Toxics Research Strategy/Multi-Year Plan Review Panel; Notification of An Upcoming Public Meeting

AGENCY: Environmental Protection Agency (EPA).
ACTION: Notice.

SUMMARY: The EPA's Science Advisory Board (SAB) is announcing a public meeting of the Air Toxics Research Strategy/Multi-Year Plan Review (Panel) to conduct a review of the Agency's Air Toxics Research Strategy/Multi-Year Plan.

DATES: July 23-24, 2003--The public meeting for the SAB Panel will begin at 9 am and adjourn no later than 5:30 pm (Eastern Time) each day. The meeting agenda and final charge questions will be posted on the SAB Web site http://www.epa.gov/sab/agendas.htm one week before the meeting.

ADDRESSES: The public meeting of the Panel will be held at the U.S. Environmental Protection Agency (EPA), 109 T.W. Alexander Drive, Research Triangle Park, North Carolina 27709. The room number is C111-C for July 23 and C111-B for July 24. For further information concerning the public meeting, please contact Dr. James Rowe, Designated Federal Officer (DFO) (see contact information below).

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further

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information regarding the public meeting may contact Dr. James Rowe, Designated Federal Officer (DFO), U.S. EPA Science Advisory Board (1400A), 1200 Pennsylvania Avenue, NW, Washington, DC 20460, telephone/voice mail: (202) 564-6488, Fax (202) 501-0582, or via e-mail at rowe.james@epa.gov. Requests to present oral comments must be in writing (e-mail, fax or mail) and received by Dr. Rowe no later than noon Eastern Time on July 18, 2003. General information about the SAB can be found in the SAB Web site at http://www.epa.gov/sab.

SUPPLEMENTARY INFORMATION:

Summary: Pursuant to the Federal Advisory Committee Act, Public Law 92-463, Notice is hereby given that the Panel will hold a public meeting to provide advice to the EPA on the Agency's Air Toxics Research Strategy and associated implementation plan (Multi-Year Plan). The dates and times for the meeting are provided above.

Background: Background on the Panel or the focus of the meeting described in this notice was provided in a Federal Register Notice published on April 30, 2003 (68 FR 23132-23133).

Availability of Meeting Materials: Copies of any available meeting materials, including a draft agenda, will be posted on the SAB Web site for this panel at: http://www.epa.gov/sab/panels/atrsmyrprpanel.html approximately 10 days before the meeting.

Providing Oral or Written Comments at SAB Meetings: It is the policy of the EPA Science Advisory Board to accept written public comments of any length, and to accommodate oral public comments whenever possible. The EPA Science Advisory Board expects that public statements presented at its meetings will not be repetitive of previously-submitted oral or written statements. Oral Comments: In general, each individual or group requesting an oral presentation at a face-to-face meeting will be limited to a total time of ten minutes (unless otherwise indicated). For teleconference meetings, opportunities for oral comment will usually be limited to no more than three minutes per speaker and no more than fifteen minutes total. Deadlines for getting on the public speaker list for a meeting are given above. Speakers should bring at least 35 copies of their comments and presentation slides for distribution to the reviewers and public at the meeting. Written Comments: Although the SAB accepts written comments until the date of the meeting (unless otherwise stated), written comments should be received in the SAB Staff Office at least one week prior to the meeting date so that the comments may be made available to the committee for their consideration. Comments should be supplied to Dr. Rowe at the address/contact information noted above in the following formats: one hard copy with original signature, and one

electronic copy via e-mail (acceptable file format: Adobe Acrobat, WordPerfect, Word, or Rich Text files (in IBM-PC/Windows 95/98 format)). Those providing written comments and who attend the meeting are also asked to bring 35 copies of their comments for public distribution.

Meeting Accommodations: Individuals requiring special accommodation to access the public meetings listed above, should contact Dr. Rowe at least five business days prior to the meeting so that appropriate arrangements can be made.

Dated: July 7, 2003.
Vanessa T. Vu,
Director, EPA Science Advisory Board Staff Office.
[FR Doc. 03-17606 Filed 7-9-03; 8:45 am]
BILLING CODE 6560-50-P

ATTACHMENT C

US ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD (SAB)
AIR TOXICS RESEARCH STRATEGY/MULTI-YEAR PLAN REVIEW (ATRS/MYP)

Meeting Location: U.S. EPA Building
109 T.W. Alexander Drive, Research Triangle Park, NC 27709
C111-C (July 23) and C111-B (July 24)

DRAFT MEETING AGENDA (July 14, 2003)

Wednesday, July 23, 2003

9:00 am	Introductory Remarks and Welcome a. Welcome and Introduction of Air Toxics Panel Members and Guests b. Committee Administration	Dr. James N. Rowe, Designated Federal Officer, SAB Staff Office
	Remarks by the SAB Staff Office Director	Dr. Vanessa Vu, Director, SAB Staff Office
	Introduction of the Topic	Dr. Fred Miller, Chair, ATRS/MYP Panel
9:20	Presentation of Overview of Air Toxics Strategy/Multi-Year Plan; Clarifying Discussion on the Reports with Panel Members	ORD Representative(s), TBA
10:30	BREAK	
10:45	Public Comments - TBA	
11:00	General Discussion of Report	Dr. Fred Miller, Chair

a. Air Toxics Research Strategy
b. Multi-Year Plan

12:00 pm LUNCH

1:15 Discussion of Charge Questions (not necessarily in order given):

a. Charge 1 – Discussant: Dr. Lippmann
b. Charge 2 – Discussant: Dr. Zeise
c. Charge 3 – Discussant: Dr. Lippmann
d. Charge 4 – Discussant: Dr. Miller
e. Charge 5 – Discussant: Dr. Levin
f. Charge 6 – Discussant: Dr. Henderson
g. Charge 7 – Discussant: Dr. Overcamp
h. Charge 8 – Discussant: Dr. Lippmann
i. Charge 9 – Discussant: Dr. Miller

2:30 BREAK

3:00 Continuation of Charge Questions Discussion — Discussants

5:30 RECESS

Thursday, July 24, 2003

9:00 am Continuation of Charge Question Discussions — Discussants

10:30 BREAK

10:45 Complete Discussion of Charges; Summation of Panel Findings — Dr. Fred Miller, Chair

12:00 pm LUNCH

1:15	Panel Writing Session for Draft Report	Panel Members
5:30	ADJOURN	

ATTACHMENT F

Charge to the Air Toxics Research Strategy/Multi-Year Plan Review Panel

A. Background

The Environmental Protection Agency (EPA) implements numerous requirements within Section 112 of the Clean Air Act (CAA) to protect the public and the environment from hazardous air pollutants (HAPs). The CAA lists 188 HAPs and there are thousands of other potentially toxic chemicals that find their way into the environment. Given concerns for the potential human health risks associated with exposures to the large number of chemicals and sources and the complexity of effects, exposure scenarios, and mitigation practices, it is widely accepted that the uncertainties associated with air toxics risk assessments and risk management decisions should be reduced.

While the scope and magnitude of a research program to sufficiently address the uncertainties in air toxics risk assessments is likely very large, the recent level of resources within the Office of Research and Development (ORD) to address these uncertainties has been fairly modest. However, it is difficult to expect increases in resources large enough to address the uncertainties for every air toxics on a chemical by chemical basis. Consequently, ORD needed to develop an efficient and effective approach to reduce these uncertainties by managing air toxics research through a multi-laboratory/center and multi-disciplinary research program.

The ORD has developed an air toxics research strategy (ATRS) and an air toxics multi-year plan (MYP) in consultation with the Office of Air and Radiation to address the scope and magnitude of air toxics research. The ATRS is presented as a conceptual approach for air toxics research, and does not contain the detail that emerges in the MYP. Both documents are being presented for review because the best understanding of ORD's air toxics research program is gained by awareness of the overarching strategy and the more specific research plan for effecting that strategy. The ATRS provides a framework and strategic principles as the basis for ORD's research directions and priorities. The MYP develops specific annual performance goals and annual performance measures of research that must be achieved in order to meet regulatory-based long term goals in air toxics research. Given the importance of the air toxics program to the EPA, ORD requests the SAB to provide review and advice on direction and management of the air toxics research program as guided by these documents.

B. The Charge to the Panel

Charge Question 1. **ATRS** - The Clean Air Act Amendments of 1990 (CAAA) mandate regulation of air toxics from mobile, stationary, and area sources. The Office of Air and Radiation (OAR) has taken many regulatory actions to comply with the CAAA and include the following: developing road and non-road mobile source regulations, designating major (stationary) source categories, developing appropriate technology standards for the source categories, determining residual

risk after these standards have been in place 8 years, designating the 33 most hazardous urban air toxics, and conducting a National Scale Assessment of air toxics. These activities are largely combined under the air toxics program known as the National Air Toxics Assessment (NATA). Given these ongoing regulatory activities, does the research strategy provide a sufficient regulatory and research context and is it on target in identifying and addressing the expected research needs of the air toxics regulatory program? In particular, is the primary purpose of the ATRS of improving the science underlying the National Air Toxics Assessment (NATA) Program (national scale assessments, "residual risk" and "urban soup"assessments, assessments that address non-inhalation exposures associated with the deposition of HAPs, and aid to states) appropriate?

Charge Question 2. **ATRS** - ORD has chosen to address the regulatory needs mandated in the CAAA using a framework that parallels the risk assessment paradigm. Thus, basic key questions aligned with research needs regarding emissions, exposure assessment, health effects assessment, risk characterization, and risk management have been developed. Do the summary key questions and research needs comprehensively address the important research that should be undertaken, given the scope of the ATRS?

Charge Question 3. **ATRS** - Assessing and managing risks from air toxics requires that the sub-disciplines of the risk assessment/risk management paradigm be effectively engaged to provide a useful result. Are all relevant discipline areas, e.g., emissions, health effects, exposure assessment, health effects, risk characterization, and risk management, addressed at an appropriate and consistent level of detail, thereby presenting a unified perspective?

Charge Question 4. **ATRS** - Given ORD's limited resources to conduct research that supports the regulatory needs of the CAAA there is a need to prioritize our research efforts. The Strategy lays out the strategic principles articulated in previous EPA and ORD strategic plans (e.g. greatest uncertainty, highest risk, multi-disciplinary research) which were employed in the ATRS along with principles more specific for meeting air toxics regulatory needs (e.g., grouping, near- and long-term research) as guiding principles by which research prioritization could be effected. Are the strategic principles listed in Chapter 2 appropriate, and do they facilitate effective decision making for prioritizing future air toxics research?

Charge Question 5. **ATRS** - With 188 air toxics, creating a strategy for air toxics research has to address two-parameters: the particular air toxic to be studied and the research need(s) for that particular air toxic. Some way to narrow the focus had to be developed, and the decision was to group the air toxics by physico-chemical characteristic and also by regulatory need. Is the draft ATRS approach of grouping air toxics (Strategic Principle #1), first by chemical characteristics and then by regulatory need, appropriate, and what other approaches might be explored to efficiently group air toxics? In an effort to show that the ATRS was

not just a concept but could actually be applied to a chemical grouping, research projects in response to the key questions are outlined for the poly-organic matter (POM) grouping. Does using the POM example (Chapter 3) help explain the kind of research and development activities and project areas that should be expected as the ATRS is implemented, or it should Chapter 3 be omitted because we now have an Air Toxics Multi-Year Plan (MYP)? MYPs were not in place at the time the ATRS was developed.

Charge Question 6. **ATRS** - Implementation of the direction outlined in the ATRS is necessary to achieve the intended research that will support the regulatory needs of the CAAA. Three implementation approaches were developed: an Air Toxics MYP, cross-laboratory steering committees, and scientist-to-scientist meetings. The intent of the MYP is to lay out precisely the long-term goals, critical paths of research, annual performance goals, and annual performance measures to support the air toxics regulatory needs. Cross-laboratory implementation committees will help integrate and specifically designate projects and investigators to conduct research projects. Scientist-to-scientist meetings will continually update OAR and ORD on research progress and help highlight new and emerging directions for air toxics research. Are the implementation approaches of developing an air toxics multi-year plan, creation of a cross-laboratory and center air toxics steering committee, and conduct of scientist-to-scientist meetings on air toxics research sufficient to implement the ATRS?

Charge Question 7. **MYP** - As the MYP was developed, the intention was for it to reasonably follow from the ATRS. The foundation of the MYP is the two Long-Term Goals (LTGs). Thus, the segue from the ATRs to the LTGs should be seamless. Do the long-term goals of the MYP align with the ATRS, and do they support the priority needs of the program and regional offices? Would accomplishing these LTGs enable ORD to meet the Air Pollution Research Sub-Objective stated as follows: air toxics research will develop and improve air quality models and source receptor tools, cost effective pollution prevention and other control options, and scientific information and tools to understand and characterize environmental outcomes associated with nationwide, urban, and residual air toxics risks?

Charge Question 8. **MYP** - The Government Performance and Results Act (1993) mandates government agencies to develop general goals and objectives and outcome goals and objectives for their programs. Under EPA's Clean Air Goal (1), ORD's research is described under the Science/Research Objective (1.5) and the Air Pollution Research Sub-Objective (1.5.2). The MYP establishes two air toxics LTGs under this Sub-Objective. The critical paths to achieve these LTGs are composed of outcome oriented annual performance goals (APGs), and the outputs for these APGs are annual performance measures (APMs). Are the LTGs appropriate for meeting the Air Pollution Research Sub-Objective (see 7 above)? Are the APGs and APMs measurable outcomes and outputs,

respectively? Do the APGs develop a critical path to achieve the LTG? Do the APMs encompass a body of research that "adds up" to logically achieve the APG?

Charge Question 9. **MYP** - Resources to accomplish air toxics research in ORD has been steady at approximately $20M, which includes approximately 90 FTE, for several years. No STAR grants have been awarded since FY 2000. The FY 2003 budget disposition is as follows: (Exposure - $4.6M; Health Effects - $4.3M; Risk Assessment - $3.6M; Risk Management - $1.7M; Health Effects Institute - $1.9M; and Administrative - $3.8M). Are these resources sufficient to provide air toxics research that will achieve the LTGs and thereby support the regulatory needs mandated by the CAAA?